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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 03072011

Application Number: 10/796,239
Filing Date: March 9, 2004
Appellant(s): Lee, Fred T. et al

Keith M. Baxter
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 22, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

U.S. Patent Application No. 10/167,681; Appeal No. 2009014945

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application: 1-9, 13, 16-22, and 28-32.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION.

WITHDRAWN REJECTIONS

Claims 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on "the first and second electrode set each comprising 3 wires positionable at angularly offset radial points around the shaft configuration".

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Listing of Evidence Relied Upon

The following is a listing of the evidence (e.g. patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Number (Title)	Name	Date
5,728,143	Gough et al	March 17, 1998
6,488,679	Swanson et al	December 3, 2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-9, 13, 16-22, and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al ('143) in combination with Swanson et al. Gough et al ('143) teach a device as claimed except for the specific disclosure that the current is passed from one electrode set to the other and the specific frequencies claimed. Swanson et al teach using frequencies in the 1 KHz range, to which tissue has a high resistivity. It would have been obvious to the artisan or ordinary skill to employ the frequencies in the 1 KHz range, since these are frequencies to which tissue has a high resistivity, as taught by Swanson et al, and would thus produce more heating, and to configure the device to produce current flow in the axial direction when there are multiple electrodes, since this would ablate the tumor more quickly than the procedure involving rotation, discussed by Gough et al ('143), and to provide multiple sets of electrodes with at least three electrodes, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and is merely the provision of

multiplied parts for multiplied effect, to provide each shaft as a insulated metallic tubular member in a coaxial configuration, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and would make the device more sturdy, to provide the two sets of electrodes at a fixed predetermined distance, for example by providing trocars of different fixed lengths to be used together, since this would assure that the preset distance was not altered on insertion of the device or during the procedure, and to provide the insulating sleeve along at least the length of the trocar between the two sets of antenna, since this would prevent current from being grounded through the trocar, and to employ the trocars in a side by side configuration, rather than coaxial, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and would enable independent placement of the trocars, thus producing a device and method such as claimed.

(10) Response to Argument

I) The Drawing Objections

It is apparently asserted by appellant that the drawing objection is improper. However, the objection to the drawing is just that – an objection (see MPEP 608.02(g)). Objections are petitionable matters to the Director of the Patent Office (see MPEP 1002) and is not properly before the Board (see MPEP 1201).

II) Rejection Of Claims 30-32 As Failing To Comply With The Written Description Requirement Under 35 USC 112 1st Paragraph

This rejection has been withdrawn.

III) Claims 1-9, 13, 16-22, And 28-32 Are Properly Rejected Under 35 U.S.C. 103(a) As Being Unpatentable Over Gough ('143) in Combination With Swanson et al

A) Response To Arguments That Axially Spaced Sets Of Three Radially Extending Electrode Tips Are Not Taugh By The Prior Art

Firstly, appellant asserts that as "generally agreed by Applicant and the Examiner, neither Gough nor Swanson teach axially spaced sets of three radially extending electrode tips. *See Final Office Action, page 13, first sentence of the final paragraph.*" (see the instant Brief, the first two sentences of the second full paragraph on page 8, italicized text in original). This statement is not entirely correct. The referred to sentence in the rejection mailed in April 2, 2010 actually reads:

> "As to the limitation of two sets of three electrodes defining two respective axially spaced apart planes, it is the examiner's view that it would be obvious to modify e.g. the embodiment shown in Figures 5 or 8 to include 3 electrodes, due to both the obviousness of providing duplicate parts for multiplied effect (as determined in *St. Regis v. Bemis*, cited above) and the explicit teaching of providing more than 2 (i.e. 3, 4, 5, 6, or more) electrodes, as set forth in column 3, lines 20-25 of Gough et al ('143), discussed above"

Which sentence was not intended to convey that Gough ('143) does not teach axially spaced sets of three radially extending electrode tips, although admittedly there is no illustration of this particular embodiment in Gough ('143). The configuration is fairly taught thereby, given the disclosure at column 3, referenced above, in conjunction with e.g. the embodiment illustrated in Figure 8 thereof. It is well understood that "[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." In re Preda, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968) (A process for catalytically producing carbon disulfide by reacting sulfur vapor and methane in the presence of charcoal at a temperature of "about 750-830°C" was found to be met by a reference which expressly taught the same process

at 700°C because the reference recognized the possibility of using temperatures greater than 750°C. The reference disclosed that catalytic processes for converting methane with sulfur vapors into carbon disulfide at temperatures greater than 750°C (albeit without charcoal) was known, and that 700°C was "much lower than had previously proved feasible.")" (see MPEP § 2144.01). Thus it is the examiner's view that Gough ('143) implicitly discloses "axially spaced sets of three radially extending electrode tips" as claimed.

Next appellant asserts that the examiner "attempts to account for the failure to find axially spaced sets of three radially extending electrode tips" using what appellant alleges are "conclusory statements such as the element being "not critical"; within the scope of one of ordinary skill in the art" and providing "no unexpected result" and being "merely the provision of multiplied parts for multiplied effect" (see the instant Brief, the third full paragraph on page 8, terms in double quotes in original). Then appellant asserts that the "rejection is disconnected form the legal standards for patentability under 35 U.S.C. § 103(a)" and citing MPEP § 2141. While there is no per se discussion of the criticality of a feature in § 2141, this does not preclude the determination of critical features in the determination of the propriety of an obviousness rejection. For example, it is understood that appellant could have rebutted "a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range." (see MPEP § 2144.05(III)). Interestingly, the statement that the provision of multiple three electrodes is "not critical" etc. was first put on the record in the Office Action mailed December 23, 2008. However, despite having filed a Rule 1.132 Declaration in the case on December 18, 2009, nearly a year subsequent to the statement by the examiner regarding criticality, etc., Declarant made no statement regarding criticality or unexpected results related to this particular electrode

configuration, nor were comparative results of the claimed configuration verses Declarant's perception of the configurations disclosed by Gough ('143). Thus not only is the issue of the criticality of the claimed electrode configuration (i.e. the range of 3 or more electrodes verses the electrode configuration of Gough ('143)), and any unexpected results flowing therefrom proper for an obviousness inquiry under 35 U.S.C. 103(a), as set forth above regarding MPEP § 2144.05(III), but appellant could have set the matter to rest, if he so chose, by including test results in the Declaration filed almost a year subsequent the examiner's statement of non-criticality.

The rationale behind appellant's assertion that the rejection is "disconnected from the legal standards of patentability" eludes the examiner, especially in view of appellant's statement in the paragraph bridging pages 8 and 9 of the instant Brief: "While unexpected results can be used to show obviousness, an assertion of a lack of unexpected results is not a basis for a rejection under obviousness" (see the instant Brief, the last full sentence on page 8). Logically, if unexpected results can be used to show nonobviousness, there must be a situation wherein the *prima facie* showing of obviousness is sufficiently strong to warrant the showing of unexpected results to rebut the *prima facie* case. In the instant case, where the difference between the prior art (specifically Figure 5 of Gough ('143)) and the claim, with respect to the two sets of electrodes, is the mere addition of additional electrodes to the existing sets, and where the reference itself explicitly states that the number of electrodes can be varied (see e.g. the above cited passage in column 3), is, in the examiner's view, just such a situation. Thus contrary to appellant's assertion, the examiner has not used the "assertion of a lack of unexpected results...[as]…a basis for rejection under obviousness" In fact it is the explicit and implicit

teachings of the references which provide the basis for the rejection, the lack of unexpected results being simply observed on the part of the examiner, as failing to contravene the *prima facie* showing of obviousness.

Similarly, the examiner's noting that the addition of other electrodes to the distally and proximally located sets in Figure 5 being "within the scope of one of ordinary skill in the art, is not solely based on this principle, but is based on the combination of this fact with the explicit and implicit teachings of Gough ('143), particularly the teaching of providing varying numbers of electrodes, as discussed in column 3 thereof, as set forth above. It is interesting to note, that despite the examiner having particularly pointed out this passage in Gough ('143) as early as the Office Action mailed June 24, 2009 (see the last sentence on page 3 and the quoted text spanning pages 3 and 4 of that Action), appellant has studiously avoided presenting any arguments with respect to the teaching that the number of antennae can be varied at column 3 in Gough ('143), instead focusing on the examiner's ancillary observations, which, in combination with the disclosures in Gough ('143), establish a *prima facie* case of obviousness, with regard to this teaching.

Regarding the provision of multiple parts for multiplied effect, appellant asserts that the examiner's position is unsupported by *St. Regis*. Regardless of this, however, the examiner's position is supported by *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) wherein the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced (see MPEP 2144.04(VI)(B)). No new or unexpected result having been shown, this argument is not convincing.

Concluding, appellant asserts that in "the above formal rejections, the Examiner has failed to provide any analysis supporting this rejection that would permit Applicant the opportunity to rebut the Examiner's reasoning" (see the instant Brief, the first sentence of the last full paragraph on page 9). The examiner must respectfully disagree. The examiner provided the degree of analysis that he felt was sufficient to convey the manner in which the art was combined and interpreted to read on the claims to which it is applied. If it appeared that the examiner overestimated appellant's ability to discern this, based on the arguments presented in response to the examiner's rejection, the examiner then provided a further, more detailed (i.e. more explicit) explanation of the manner in which the references were being interpreted. It is noted that appellant's assertion that, with reference to § 2143, that "the court in KSR International Co. v Teleflex Inc. 82 USPQ2d 1385 (Supreme Court, 2007) requires that the analysis supporting a rejection under § 103 be made explicit" (see the instant Brief, the last sentence of the last full paragraph on page 9, italics in original), is inaccurate. In fact § 2143 states "[T]he Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 **should** (not must or shall) be made explicit" (emphasis and parenthetical comments added). It is interesting to note that there is no requirement as to where the explicit analysis should be – that is no requirement that it be "in…the formal rejections" as alleged by appellant, thus the placement of such analysis in the response to arguments in the office action is entirely proper. It is also interesting to note the immediately succeeding sentence in the opinion as well: "[A]s our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ" KSR International Co. v

Teleflex Inc. 82 USPQ2d 1385, 1396 (Supreme Court, 2007). Given the explicit statement of increasing the number of electrodes as desired in Gough ('143), appellant appears to be arguing from the position that one of ordinary skill in the art is not only not capable of drawing inferences from the teachings of the references, but incapable of following explicit direction therein as well.

B The Outer Surface Between The Electrode Sets Is Insulated

Firstly, appellant asserts that as "generally agreed by Applicant and the Examiner, neither Gough nor Swanson teach that the outer shaft surface between the electrode sets is insulated. *See Final Office Action, page 14,the final paragraph.*" (see the instant Brief, the last two sentences on page 8, italicized text in original). Presumably this citation refers to the paragraph spanning pages 14 and 15 of the Office Action. This statement is inaccurate. It is firstly noted that the Office Action mailed February 27, 2008 specifically states:

> "With regard to the art rejection, applicant asserts that Gough et al ('143) does not teach an insulative member between the two sets of electrodes therein. The examiner must respectfully disagree. Firstly, Gough et al ('143) do teach the use of an insulative sleeve, 18, as noted by applicant. Taking the totality of the disclosure of Gough et al ('143), along with the knowledge of one of ordinary skill in the art, the use of this sleeve at least along the length of the trocar at least between the two sets of antennas disclosed by Gough et al ('143), is fairly taught therein. Firstly, it is noted that Gough et al ('143) was derived from a parent application, as a continuation in part, the parent application maturing in U. S. Patent No. 5,683,384, which specifically refers to the element 14 in the drawings thereof as a "primary antenna". Clearly the conversion of this element to a "trocar" in Gough et al ('143) is intended to convey that this element is can be used for purposes other than to send or receive energy. Secondly, column 5, lines 48-55, discusses that the insulating sleeve can be positioned around the trocar and can have one or more apertures, which permit the introduction of the antennas through the trocar and the insulating sleeve. Thirdly, in the discussion of Figure 4 at column 8, lines 1-4, Gough et al ('143) discuss a configuration wherein a lesion is produces "with a minimal central core that is not ablated." Thus clearly Gough et al ('143) were aware of the ability of the ability of the trocar to sink electrical current, if it was metal, and to provide an arrangement where an insulating sleeve

> could be deployed thereon to prevent the current from heating the tissue adjacent the trocar, should that be desirable."

Clearly, this statement, which is also reproduced the subsequent Office Action mailed July 10, 2008 (see the passage bridging pages 2 and 3 thereof), cannot be properly characterized as "agreed upon by Applicant and the Examiner that neither Gough nor Swanson teach that the outer shaft surface between the electrodes is insulated" as alleged by appellant. The referred to paragraph in the rejection mailed in April 2, 2010, discussed on page 10 of the Brief actually reads:

> "With regards to the limitation of "insulation of a support shaft between two electrode sets", as set forth above, it is the examiner's view that the provision of an additional device of any of the types taught by Gough et al ('143) in e.g. a side by side (or other) configuration would have been obvious to the artisan of ordinary skill in the art, given the obviousness of providing duplicate parts for multiplied effect, as set forth above, and additionally, as already set forth, one of ordinary skill in the art is a surgeon familiar with radiofrequency ablation of tumors, and as such, the training for one of ordinary skill in the art would require not only 12 years of primary and secondary school, but 4 years of college, 4 more years of medical school, and additional years as an intern before qualifying as a surgeon qualified to ablate tumors with radiofrequency energy. Therefore, of necessity one of ordinary skill in the art would also be familiar with basic electrical principles, such as the relationship of current and power, the tendency for current to flow along many available paths, the appropriate connections required to cause electrical energy to be applied at the desired locations, the ability of insulators to block the flow of electrical energy, and the desirability of having the flow of energy blocked in certain locations and situations. Having established the level of skill of one of ordinary skill in the art, the information one of ordinary skill in the art would glean from the teachings of Gough et al ('143) will be determined. The establishment of the teaching and/or obviousness of providing at least three electrodes in each "set" and bipolar energization of the two sets with respect to one another have already been established

above. Gough et al ('143) also teach that the electromagnetic delivery surface may be varied by varying the amount of the trocar and or antennas that are covered by the insulative sleeve, and that the insulative sleeve can contain apertures that permit the passage of antennae through the insulative sleeve while it is in place on the trocar, see column 5, lines 48-55:

> "An insulation sleeve 18 may be positioned around an exterior of trocar 14 and/or antennas 16. All or some of insulation sleeves 18 may be adjustably positioned so that the length of an antenna electromagnetic energy delivery surface can be varied. Each insulation sleeve 18 surrounding a trocar 14 can include one or more apertures. This permits the introduction of a antenna 16 through trocar 14 and insulation sleeve 18.""

Clearly there is an implicit teaching, if not an explicit one, to provide insulation on the device wherein current is not desired to flow. As discussed in the Office Action mailed April 20, 2010, the teachings of Gough ('143) demonstrate that one of ordinary skill in the art understands the function of insulators and how they are applied to conductive surfaces in order to configure the path of least resistance to be between the energized antennae, rather than the antenna(e) and the trocar, if so desired.

Continuing, appellant asserts that the examiner's motivation of making the device more sturdy "is not disclosed by the prior art of record and the Examiner has provided no basis to suggest that it was a motivation generally recognized in the prior art at the time of the invention" (see the instant Brief, the second sentence of the first paragraph on page 10). However, this is not required. As clearly set forth in MPEP 2143(G): "[A]n implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the improvement' is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is **stronger** (i.e. more sturdy), cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance

commercial opportunities by improving a product or process is universal-and even common-sensical - we have held that there exists in these situations a motivation to combine prior art references even absent any hint of suggestion in the references themselves. In such situations, the proper question is whether the ordinary artisan possesses knowledge and skills rendering him capable of combining the prior art references." (citing *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1651 (Fed. Cir. 2006)). Thus no disclosure of such motivation in the prior art is required, contrary to appellant's assertion. Further, appellant brands the examiner's additional motivation as "fundamentally implausible" asserting that one of ordinary skill in the art would not use low-strength, relatively easily abraded insulation to make a metal shaft sturdier (see the instant Brief, the last sentence of the first full paragraph on page 10). However, nowhere in Gough ('143) is appellant's conjecture that the insulation need be low-strength or easily abraded borne out. To the contrary, the insulating material of Gough ('143) is taught as being sufficient to contain, support and allow the deployment of the umbrella electrodes (see e.g. Figure 8) and thus must be of greater rigidity than the electrodes, else it would be deformed thereby.

Further, appellant argues that the examiner's stated motivation of preventing current from being grounded through the shaft is also "not recognized in the cited prior art nor does the Examiner has provided any basis for a belief that this was a motivation held by those of ordinary skill in the art at the time of the invention" (see the instant Brief, the second sentence of the second full paragraph on page 10). The examiner must respectfully disagree. Again, assuming normal intelligence on the part of one of ordinary skill in the art, it would become fairly obvious relatively quickly to the physician employing the device of Gough ('143) that the RF current,

which is of high enough value to cause tissue ablation, which is returning via the handle, which the surgeon must hold in order to provide the "up and down, rotated about its longitudinal axis, and moved back and forth" movement (see Gough ('143) column 4, lines 61-63), that not providing insulation thereon produces undesirable results. Further, Gough ('143) specifically states "An insulation layer may be positioned in a surrounding relationship around at least a portion of an exterior of the trocar. A distal end of the insulation at the distal end of the trocar can be removed. This creates an electromagnetic energy delivery surface at the trocar's distal end. The trocar then becomes at least partially an antenna" (see column 3, lines 28-35). Clearly from this disclosure, one of ordinary skill in the art understands the manipulation of the current path of the surgical energy using the configuration of the insulators applied to the antennae. Also clearly Gough ('143) states that the insulation at the end of the trocar can (not must) be removed to provide an energy delivery surface. Equally clearly, if the insulation is not removed, no energy delivery surface at the distal end of the trocar will exist, and the energy will be transferred in a bipolar fashion between two antennae. This is seen, for example, in the disclosure relating to Figure 5: "Multiple antenna device 12 can be operated in **the bipolar mode between the two antennas 16** or between a antenna 16 and trocar 14" (see column 8, lines 9-10, emphasis added). Thus Gough ('143) undeniably teaches bipolar operation between two axially separated antennae.

Next appellant argues, with regard to the examiner's statement that insulating the trocar would be motivated by the desire to prevent current from being grounded through the trocar, "[T]o the contrary, Gough teaches away from this motivation by describing multiple systems none of which provide insulation at this location and further describing embodiments where

current flows through the shaft" (see the instant Brief, the third sentence of the second full paragraph on page 10). Thus, while it is true that Gough ('143) teach other embodiments of the device wherein it is desirable to have the current pass through the trocar, this cannot remove from Gough ('143) the express teaching to operate the device with the current passing only through the electrodes, and not the trocar, as unequivocally stated in the passage at column 8, reproduced above. The express statement regarding the contemplated insulation placement on the trocar explicitly states that removing the insulation creates an electromagnetic energy delivery surface at the trocar's distal end and that the trocar then becomes an antenna: "[A]n insulation layer may be positioned in a surrounding relationship around at least a portion of an exterior of the trocar. A distal end of the insulation at the distal end of the trocar can be removed. This creates an electromagnetic energy delivery surface at the trocar's distal end. The trocar then becomes at least partially an antenna" (see column 3, lines 28-35). Thus any argument based on Gough ('143) teaching away from insulating the entire trocar shaft must fail.

Proceeding with this imaginative line of reasoning, appellant then asserts that Gough "addresses any potential for short circuiting by insulating the lower portions of the antennas 16…further teaching, contrary to the examiner's proposed modification, that such insulation is not required to prevent shorting" (see the instant Brief, the penultimate sentence of the second full paragraph on page 10). According to appellant's rational, the shorting of the electric current to the trocar is prevented by insulating the lower portions of the antenna. Thus, in appellant's schema, apparently it is possible for the trocar to short the current to ground, and this is prevented by the use of insulation. Apparently, however, this (the shorting of current to ground by the trocar) is only possible when the current is travelling through the lower part of the

antennae, for when it travels into the tissue through the exposed upper portion of the antennae (i.e. the energy delivery surface) then the electrical current somehow (without the use of insulation on the trocar) will not be grounded through the trocar. Except, of course, when the trocar is desired to be used as part of the bipolar circuit, in which case the RF energy will be grounded through the trocar, despite the fact that the configuration of the trocar and antennae combination is (according to appellant's assertions) exactly the same, i.e. with no insulation on the trocar, and only insulation on the lower parts of the antennae. While this mode of operation proposed by appellant – that the RF current goes to whichever element of the applicator (trocar or the other antenna), apparently on the basis of the surgeon's desires, rather than the physical configuration of the device, would undoubtedly be convenient, however, it is neither supported by the physics of electricity, as it is currently understood, nor the teachings of Gough ('143). As set forth above with respect to the passage at see column 3, lines 28-35, Gough ('143) expressly teach that the current flow to the trocar is controlled by the configuration of the insulation on the trocar, which requires the absence of insulation to implement and energy delivery surface on the trocar. Logically, as would be immediately apparent to one of ordinary skill in the art, the provision of insulation thereon prevents the trocar from becoming an energy delivery surface, i.e. it will not have current flowing through it. Thus appellant's arguments are not convincing.

IV) Claim 8 Is Properly Rejected Under § 103

Regarding claim 8, appellant notes that the claim requires two sets of three electrodes each, wherein the tips of the corresponding electrodes in each set are aligned (see the instant Brief, the first paragraph on page 11).

Next appellant alleges that the examiner "generally dismisses the claim limitation directed to the number of electrodes under the improper "multiplicity principle" described above and does not consider the limitations of alignment or their angular separation" (see the instant Brief, the first sentence of the second full paragraph on page 11). The examiner must respectfully disagree. The embodiment shown in Figure 5 of Gough ('143) undeniably discusses a subspecies entailing using the two antennae in a bipolar configuration: "[R]eferring now to FIG. 5, a center of selected tissue mass 28 is pierced by trocar 14, antennas 16 are laterally deployed and retracted, trocar 14 is rotated, antennas 16 are deployed and retracted, and so on until a cylindrical ablation volume is achieved. Multiple antenna device 12 can be operated in the bipolar mode between the two antennas 16, or between a antenna 16 and trocar 14. Alternatively, multiple antenna device 12 can be operated in a monopolar mode" (see column 8, lines 5-12). Thus the use of two sets of electrodes with each set containing one electrode, which is aligned with the other is taught by this passage in Gough ('143). Gough ('143) also teaches in general that "[T]he number of deployed antennas can be four, five, six or more. Some of the antennas can be deployed out of the distal end of the trocar, while other antennas may be deployed from ports formed in the trocar along its longitudinal axis" (see column 3, lines 20-23). Thus the provision of more than one antennae, with a specific reference to embodiments of the form shown in Figures 5 and 8, in each set is also explicitly taught by Gough ('143). However, even if this explicit teaching in Gough ('143) were not present, the duplication of parts without a new or unexpected result is not of patentable significance (see *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and MPEP § 214404(VI)(B)). And even ignoring this, there is still motivation to provide multiple antennae in each set (each being aligned as the antenna in each set are in the

embodiment of Figure 5) since "[A]n implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the improvement' is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, **faster,** lighter, smaller, more durable, or **more efficient**. Because the desire to enhance commercial opportunities by improving a product or process is universal-and even common-sensical- we have held that there exists in these situations a motivation to combine prior art references even absent any hint of suggestion in the references themselves. In such situations, the proper question is whether the ordinary artisan possesses knowledge and skills rendering him capable of combining the prior art references." (see *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006), emphasis added, and MPEP § 2143(G)). Thus since the motivation may be implicit, and need not be expressly articulated in the prior art, appellant's assertion the "since the Examiner has failed to identify a motivation to modify existing methods within the prior art, the rejection of claim 8 is improper" (see the instant Brief, the last full sentence on page 11), must fail.

V) Claim 28 is Obvious Over Gough ('143) in Combination With Swanson

Turning to the rejection of claim 28, appellant argues that , with regard to the limitation of two concentric tubes, each having a tubular metal inner portion and an insulated outer portion, "[T]he Examiner does not address this limitation in applying § 103 to claim 28" (see the instant Brief, the first sentence of the second full paragraph on page 12). The examiner must respectfully disagree. While the limitation is not specifically addressed in the body of the rejection, the examiner makes it clear in the response to attorney's arguments the manner in

which the art is interpreted to read on this particular claim limitation (see the Final Rejection mailed April 2, 2010, the first full paragraph on page 20):

> "With regard to what applicant refers to as "Factual issue No. 4", the examiner acknowledges that the provision of two shafts, each composed of a metallic inner portion and an insulated outer portion is not taught by Gough et al ('143). However, the examiner also notes that this limitation is not critical and configuring the device of Gough et al ('143) as such would have been obvious to the artisan of ordinary skill, either by providing duplicate parts (i.e. duplicate multiple antenna devices) or by altering the composition of the two sheaths in Figures 7 or 8 to include both metal tubes (for strength, support, and rigidity) and insulators (to block the current from flowing from the antennae into the support shaft via the tissue or any fluid infused, as disclosed with respect to Figure 6(c)). Applicant's assertion that the issue of criticality "is not seen to relate to combination claims in the electrical-mechanical arts unless a range or dimension is at issue" is noted, however, this assertion is erroneous. Applicant is referred to MPEP §716.02 - §716.02(g) and §2164.08(c), for example. A prima facie case of obviousness having been established by the examiner, by virtue of the rebuttal of the assertions and arguments submitted in the Haemmerich Declaration and applicant's remarks, the discussion of a lack of showing of unexpected results is appropriate. Thus this argument is not convincing."

Here again, the limitation, which has not been shown to be critical, and in fact is argued as inconsequential by appellant, due to the lack of need for any insulation on the metallic trocar to prevent the RF energy from being grounded thereby (as argued in section III of the instant Brief (see the last paragraph on page 23 of the instant Brief), is obvious, as it would make the device stronger and more durable, which motivation need not be explicitly set forth in the references (see MPEP § 2143(G)). Thus this argument is not convincing.

VI) Claim 29 Is Obvious Over Gough ('143) in Combination With Swanson

The basis of appellant's argument here is that the references do not show a configuration wherein the support shaft is formed of two tubes positioned in side-by-side configuration to provide predetermined separation between the electrode tips (see the instant Brief, the third

paragraph on page 12). However, as articulated in the Final Rejection mailed April 2, 2010 (see the last five lines on page 20):

> "With regard to what applicant refers to as "Factual issue No. 5", the examiner acknowledges that the provision of two shafts in a side-by-side configuration is not explicitly taught by Gough et al ('143), however, as set forth above it is an obvious variation of the Gough et al ('143) device and method, as it would save time over the use of a single device that was then moved around, and merely constitutes the provision of duplicate parts for multiplied effect"

Again, the only difference between the prior art and the claimed invention rests in the provision of duplicate parts, the relative positioning of the two shafts being a limitation on the method of the use of the device, since no coupling structure whatsoever is recited either in the claims, or the originally filed disclosure. This has been judicially determined to be obvious, absent a showing of unexpected results (see *Harza* above and MPEP § 214404(VI)(B)), Thus this argument is not convincing.

VII) Other Arguments

1) The Teaching Of Using Multiple Electrodes

Here appellant postulates that the multiple electrodes could all be positioned at the end of the trocar. However, this ignores the express teaching in Gough ('143) that "[T]he number of deployed antennas can be four, five, six or more. Some of the antennas can be deployed out of the distal end of the trocar, while other antennas may be deployed from ports formed in the trocar along its longitudinal axis" (see column 3, lines 20-23). Thus this argument is not convincing.

2) Using Bipolar Mode To Provide Current Flow From One Electrode To Another Along The Axis Of The Device Was Known

Now appellant asserts that the examiner has taken the teachings of Gough ('143) out of context. In fact the reverse is true. Regarding this accusation, appellant states "In fact, Gough states: Multiple antenna device[s] 12 can be operated in a bipolar mode between two antennas 16. *See column 8, lines 5-12*." (see the instant Brief, the last 5 lines on page 24). It is noted that in fact the cited portion Gough ('143) reads, *in toto*: "[R]eferring now to FIG. 5, a center of selected tissue mass 28 is pierced by trocar 14, antennas 16 are laterally deployed and retracted, trocar 14 is rotated, antennas 16 are deployed and retracted, and so on until a cylindrical ablation volume is achieved. Multiple antenna device 12 can be operated in the bipolar mode between the two antennas 16, or between antenna 16 and trocar 14. Alternatively, multiple antenna device 12 can be operated in a monopolar mode" (see column 8, lines 5-12). It is further noted that the term "multiple antenna device 12" is illustrated in Figure 5 as a single device, not the multiple device that appellant attempts to infer for this embodiment.

3) Adding Additional Antennae Would Have Been Obvious

With regard to the addition of more antennae, appellant asserts that "[W]hether a particular number of additional electrodes will meaningfully improve the uniformity of heating in human tissue is far outside the expertise of the Examiner" (see the instant Brief, the first sentence of the second full paragraph on page 14). Also, appellant refers to taking of official notice. It is firstly noted that the provision of additional antennae is obvious as set forth in Harza and MPEP § 214404(VI)(B), in section II above and additionally obvious with respect to implicit motivation as set forth in *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006) and MPEP § 2143(G), with regard to the disclosure of the use of any number of antennae desired in e.g. column 3 of Gough

('143), as also set forth in section II above. Secondly, no official notice has been taken, the recognition of the fact that the use of a larger number of sources in a more disbursed arrangement, falls under the realm of common sense. Reliance on the common sense of one of ordinary skill in the art is permitted "Our suggestion test is in actuality quite flexible and not only permits, but requires, consideration of common knowledge and common sense" (*KSR International Co. v Teleflex Inc.* 82 USPQ2d 1385, 1397 (Supreme Court, 2007), quoting *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006)). While an examiner may be required to provide evidentiary support for officially noticed facts that represent common knowledge, there is no such requirement to demonstrate common sense. The fact is, if there is (just as an example) a cylindrically shaped tumor that is 3 mm in diameter, using one 1 mm diameter electrode pair at the 12 o'clock position on the top and bottom circular faces thereof will provide a less uniform field of current in the tumor than two such sets at 12 o'clock and 6 o'clock, which in turn will provide a less uniform field than 3 such sets at the 12, 4, and 8 o'clock positions, etc.

4) Gough ('143) teaches many variations

Next appellant asserts that the examiner implicitly argues that all readily implemented versions of the devices disclosed by Gough ('143) are unpatentable. The examiner has done nothing of the kind. The examiner has provided motivations for each modification of the devices disclosed by Gough ('143), for example the modification of the device as shown in Figure 5 of Gough ('143) to provide multiple (e.g. 3) electrodes at each of the axial locations, as discussed in section III) (A) above, would enable speedier treatment, since the repeated extension, ablation, retraction, and rotation steps need not be repeated 3 times, instead, only one extension, ablation

and retraction cycle need be performed and no rotation step is necessary. Similarly, the provision of a metallic center portion and an insulative outer portion of the two shafts, as discussed in III) (B) above, would yield a device which is stronger by virtue of the combination of metal and insulation, which motivation is permissible as set forth in MPEP 2143(G), and would enable the blocking of current flow to the trocar, which is desired in some of the embodiments disclosed by Gough ('143).

Next appellant attempts to cast the examiners rejection of the claims in terms of the disclosure of a genus rendering all species obvious. However, the examiner has never relied on this principle and nowhere in the prosecution history of the instant application has set this forth. The examiner has relied on proper and well known motivations, or the teachings of Gough ('143) itself) as the basis for modification of the various disclosed embodiments of Gough ('143) applied to the claims. Thus appellant's reliance on the holding in *Baird* is misplaced.

5) The Level Of Ordinary Skill In The Art Is High

Here appellant asserts that the examiner has attempted to "avoid the burden of proof in establishing obviousness of the invention simply by arguing that the level of skill in the art is high" (see the instant Brief, the first sentence of the second full paragraph on page 15). The examiner must respectfully disagree. The examiner has merely pointed out the high level of skill in order to show how the teachings of Gough ('143) would be interpreted by one of ordinary skill in the art. Continuing appellant asserts that "it is highly questionable that medical doctors, despite their years of schooling, are experts in the field of electronics or understand how radiofrequency electric currents flow through tissue to the extent that all improvements in these

devices would be obvious to them" (see the instant Brief, the second sentence of the second full paragraph on page 15). The examiner must respectfully disagree. Firstly, the examiner has at no time maintained that one of ordinary skill in the art (as appellant puts it "medical doctors") are experts in the field of electronics. In fact, the examiner has merely noted a fact stated by Gough ('143) – that one of ordinary skill in the art would understand the ability of insulators to block electrical current flow. Secondly, the examiner must note that one of ordinary skill in the art is a surgeon familiar with the radiofrequency ablation of tumors, as set forth in III)(B) above, and as such will have some understanding of how radiofrequency currents flow through tissue, this is also reflected in the teachings of Gough ('143). Thirdly, the examiner has never asserted that the level of skill is so high that all improvements to radiofrequency ablation devices are obvious.

Then appellant refers to the "affidavit (sic, declaration) by the inventor providing factual basis for the non-obviousness of the present invention at the time of the invention to those of ordinary skill in the art that has not been rebutted by any objective factual presentation by the examiner" (see the instant Brief, the last sentence of the second full paragraph on page 15). The examiner must respectfully disagree. The examiner has rebutted the assertions made by Declarant, using factual showings such as the explicit and implicit teachings of the Gough ('143) reference. The examiners analysis and discussion of the Haemmerich Declaration is reproduced herein for appellant's benefit:

> "The instant response includes a Declaration (hereinafter the "Haemmerich Declaration") by Dr. Deiter Haemmerich (hereinafter "Declarant"). The examiner will now evaluate the Haemmerich Declaration.

In paragraphs 1-5 Declarant identifies himself, noting that he is one of the instant inventors, and enumerates his education, positions he has held, issued patents, and peer-reviewed articles which he has published. In paragraph 6, Declarant asserts he has reviewed the previous office action and the references applied therein, noting that the reference to Gough applied to the claims was printed with Rita Medical Systems, Inc. as the assignee. In paragraph 7, Declarant asserts that he has been requested to comment the examiner's assertion that it would have been obvious at the time of the invention to the artisan of ordinary skill to provide each shaft as an insulated metal tubular member in a coaxial configuration, and to provide an insulated portion, and to provide an insulated portion of the trocar between two sets of antennae. In paragraph 8, Declarant states that his understanding claim 28 depends from claim 16 and that he understands the limitations of claim 16. In paragraph 9, Declarant asserts that he understands the limitations of claim 28. In paragraph 10, Declarant asserts familiarity with Rita Medical equipment, as such equipment was part of the starting materials for construction of "our prototypes of our invention" and Declarant further notes that the Rita Medical equipment "could not be used…without significant modification". In paragraph 11, Declarant provides a sketch of a Rita Model 30 probe, as of the year 2000, noting that it "can be referred to as an electrode set". In paragraph 12, Declarant asserts that in "these probes" (presumably the Rita Model 30 probes) power is applied between at least one of the electrodes and a grounding pad. In paragraph 13, Declarant asserts that he was unaware of any "devices with multiple electrode sets" that were commercially available in the year 2000. Declarant further asserts that "these electrode

sets were designed to be used one set at a time", but provides no evidentiary showing of this, such as an admonition in the product literature not to use more than one electrode set at a time. Continuing, Declarant asserts that in the year 2000 two electrode sets were used, and required the modification of insulating the an upper end of the shaft of the electrode set that protruded beyond the shaft of the other electrode set, and that power was applied between the two electrode sets (i.e. they were used in a bipolar mode), rather than using a grounding pad. In paragraph 14, Declarant asserts that there was nothing in the "product offerings" (presumably the literature accompanying the products ordered as raw materials) that suggested the use of two electrode sets together; that they be configured in a coaxial or side by side configuration; or that suggested using them in a bipolar mode. Declarant then stats "In fact, all known radiofrequency ablation devices available in the year 2000 required a grounding pad, and there was no known commercial device of this type available for operating in a bipolar mode at that time" (presumably the term "known" is intended to be read "known by Declarant"). Declarant then concludes that that Declarant sees nothing to support the examiner's finding referred to in paragraph 7 of the Haemmerich Declaration. In paragraph 15, Declarant asserts he has reviewed the Gough et al ('143) reference particularly column 7, lines 21-30 thereof, and opines that one of ordinary skill in the art would not conclude that this was referring to using two electrode sets. In paragraph 16, Declarant asserts he has reviewed the Gough et al ('143) reference particularly Figures and 8, and column 7, lines 21-34, and the remainder of the Gough et al ('143) reference, and opines that one of ordinary skill in the art at the time of the invention would not

conclude that this was referring to coupling a power supply between two electrode sets to apply bipolar power. In paragraph 17, Declarant asserts that he has reviewed the passage at page 6, lines 14-22 of the previous office action. In paragraph 18, Declarant asserts that on review of Gough et al ('143) "all instances of reference number 14 refer to a trocar that is uninsulated" and when "an insulating sleeve is added, it always has the reference number 18" and Declarant further notes that this is consistent with the construction of the Rita Model 30 and opines that it "cannot be concluded that the upper end of trocar 14 in Fig. 4 is insulated from the description of the embodiment of Fig. 4" and asserts that "In fact, it would not be possible to obtain the heating zone shown as a dashed ellipse in Fig. 4 if trocar 14 was insulated" and also notes that there is no suggestion of insulation on the tip of the device in Figure 8. In paragraph 19, Declarant asserts that the subject matter of claim 29 would not be obvious for the same reasons and further because the side by side configuration allows improved positioning of the two electrode sets to better conform to tumor geometry. In paragraph 20, Declarant asserts that once "the Gough et al. '143 patent is properly understood in view of the commercial embodiments of its assignee known in the period from 1995 to 2000, the findings in the Office action referred to above are not reasonable readings of what one of ordinary skill in the art would understand from the Gough et al. reference" and notes that Sawnson adds nothing to change that conclusion.

Having evaluated the Haemmerich Declaration, the examiner will now analyze the statements therein. The examiner has no comment regarding the contents of paragraphs 1-10. Regarding Declarant's assertions contained in paragraph 11, among

them the "Rita Model 30, which can be referred to as an electrode set" the examiner notes that while this device can be referred to as "an electrode set" that for the purposes of patent examination, the language of the claims is given it's broadest reasonable interpretation. The examiner further notes that, while the term "electrode set" appears many times in the originally filed disclosure, the term itself is never explicitly defined, thus it is given it's broadest reasonable interpretation. The meaning of the term "electrode" is simply a conductive element that is used to transmit electrical energy to or from an electrical circuit from or to an external body, which could be another electrical circuit or could also be a living body. The term "set" means "a group of things of the same kind that belong together and are so used" (*American Heritage Dictionary*). The examiner has no comment regarding the contents of paragraphs 12. Regarding Declarant's assertions contained in paragraph 13, the examiner respectfully notes that, as an initial matter, the perceived lack of availability of a product on the market by itself is of little moment with respect to the evaluation of the obviousness of a claimed invention in view of a publication. There could be any number of reasons not related to obviousness which are responsible for the absence of the product in the marketplace: the product could have been available, but unknown to Declarant, for example or the product may have been manufactured, but not have passed FDA approval, or the manufacturer may have developed and desired to produce the product, but not had sufficient capital to tool up for the production of the device. Thus standing alone, the absence of a commercial product which anticipates the claimed invention is given little weight with regard to the obviousness thereof in view of a patent, even a

patent owned by an assignee which produces what Declarant feels is the closest available commercial product to that claimed either in the patent in question or the instant application. This is best illustrated by the fact that, according to the facts set forth in the Haemmerich Declaration, there is apparently no instruction or suggestion that the Rita Model 30 can be used in a bipolar mode, however, the Gough et al ('143) reference explicitly states this in a manner so clear, that even Declarant cannot dispute it: "Multiple antenna device **12** can be operated in the bipolar mode between the two antennas **16** or between the antenna and the trocar **14**." (see Gough et al ('143), column 8, lines 9-11), bolding in original). As can readily be seen from the foregoing, the state of the commercial market is completely irrelevant to a rejection based on a U. S. Patent, when that Patent explicitly provides a teaching of the claimed invention. The examiner will also respectfully note here, that at no time during the prosecution of the instant case, or any of its parent cases have the claims been rejected on the state of the commercial market at the time of the invention. Instead they have been rejected on the combination involving Gough et al ('143) and **all** the teachings therein, irrespective of whether or not the assignee of the Gough et al ('143) patent has chosen to make a device manifesting those particular teachings available via a commercial venue. Regarding Declarant's assertions contained in paragraph 14, the examiner respectfully notes that, as set forth above with respect to paragraph 13, the absence of instructions in product literature does not remove from the U. S. Patent which is actually being applied to the claims, the teachings that are clearly contained therein. For example, as was already specifically set forth in the Final Rejection mailed June 24, 2009:

"Firstly, Gough et al ('143) teach that the number of antennas can be more than six; the antennas can be deployed from the distal end of the trocar, while others, from along it's longitudinal axis; and that the device can be operated in a bipolar fashion, see column 3, lines 20-25:

"The number of deployed antennas can be four, five, six or more. Some of the antennas can be deployed out of the distal end of the trocar, while other antennas may be deployed from ports formed in the trocar along its longitudinal axis. The antennas may be RF electrodes operating in a monopolar mode, bipolar mode, or switchable between the two.""

The applied reference undeniably teaches bipolar application of power to the electrodes. Further the teachings of Gough et al ('143) that a group of six or more antennae may be disposed in the trocar and they may be situated such that "[S]some of the antennas may be deployed form the distal end of the trocar, while other antennas may be deployed from ports formed in the trocar along its longitudinal axis." The examiner notes that Figures 6A and 6B illustrate electrodes "deployed from ports formed in the trocar along its longitudinal axis" as recited in the specification of Gough et al ('143). The fact that one product from one company does not discuss this in the literature accompanying such product; the assertion of the lack of knowledge of any product available allowing bipolar or even absolute; and definitive proof of the complete absence of any product of this type available commercially fails to remove from the reference that is actually being applied to the claims the clear and unequivocal teachings set forth within the four corners of the reference, such as those teachings in the above quote. Further with reference to the electrode set as discussed with regard to paragraph 11, above, it is respectfully noted that using the broadest reasonable interpretation of the term "electrode set" the examiner could define all the electrodes

coupled to one pole of the bipolar power supply as one set, with the electrodes coupled to the other pole of the power supply as the second set. Regarding Declarant's assertions contained in paragraph 15, the examiner respectfully notes that Declarant's interpretation of the disclosure at column 7, lines 21-30 of Gough et al ('143) notwithstanding, the above quoted passage from column 3 still fairly teaches this concept, as explained with regard to paragraphs 13 and 14, above, particularly with regard to the definition of the term "electrode set". Regarding Declarant's assertions contained in paragraph 16, the examiner respectfully notes that Declarant's interpretation of the disclosure in Figures 7 and 8, and at column 7, lines 21-34 and the remainder of Gough et al ('143) notwithstanding, the above quoted passage from column 3 still fairly teaches this concept, as explained with regard to paragraphs 13 and 14, above, particularly with regard to the definition of the term "electrode set". The examiner has no comment regarding the contents of paragraph 17. Regarding Declarant's assertions contained in paragraph 18, the examiner respectfully notes that there is no requirement that the construction of a *prima facie* case of obviousness that the feature in question be illustrated, merely that it be taught. While it may not be possible to produce the illustrated heating zone if the trocar illustrated in Figure 4 were insulated along it's entire length (the examiner maintains otherwise, however, this is ancillary to the issue at hand) so too would it be impossible to produce the ablation volume explicitly described in column 8, lines 1-4, if the trocar of Figure 4 were not insulated to the tip, a fact which would have easily been recognized by one of ordinary skill n the art in the year 2000, since if it were not insulated, current would flow from

the antennae to the trocar, thereby ablating the central core And since one of ordinary skill in the art would read the Gough et al ('143) for all of its teachings, one of ordinary skill in the art would realize that the insulating of the tip was provided by some structure, for example, the structure disclosed in column 5, lines 47-51: "[A]an insulation sleeve may be positioned around an exterior of trocar 14 and/or antennas 16. All or some of insulation sleeves 18 may be adjustably positioned so that a length of antenna electromagnetic energy delivery surface can be varied." Clearly if there is an adjustable sleeve on the trocar, it can be adjusted to cover the distal end, so as to allow the configuration in Figure 4 to be modified so as to be able to produce the ablation volume described in association therewith. With regard to the second point reproduced in paragraph 17, Declarant asserts that Figure 5, mentioned in the reproduced text, "does not suggest that two electrode sets each having a tubular member inner portion and an insulated outer portion and where the first support shaft is disposed within the second support shaft to provide a concentric tube configuration, as describe ion claim 28" since the discussion reproduced by Declarant was only directed to the length of insulation on the trocar, the lack of teaching other structures that were not directly related to the length of the insulation on the trocar is hardly surprising and does not serve to illustrate any deficiency in the examiner's line of reasoning. Regarding Declarant's assertions contained in paragraph 19, the examiner respectfully notes that in the examiner's view, the various teachings of Gough et al ('143) set forth above and in all the previous office actions, coupled with the level of skill of one of ordinary skill in the art, as set forth in the non-final rejection mailed December 23, 2008, and reproduced

in the final rejection mailed June 24, 2009 and reproduced again here for applicant's convenience:

> "the teachings of Gough et al ('143) must be evaluated for all it teachings one of ordinary skill in the art, and not merely the preferred embodiments (see *In re Boe* 149 USPQ 507). One of ordinary skill in the art is a surgeon familiar with radiofrequency ablation of tumors, and as such, the training for one of ordinary skill in the art would require not only 12 years of primary and secondary school, but 4 years of college, 4 more years of medical school, and additional years as an intern before qualifying as a surgeon qualified to ablate tumors with radiofrequency energy. Of necessity, then one of ordinary skill in the art would also be familiar with basic electrical principles, such as the relationship of current and power, the appropriate connections required to cause electrical energy to be applied at the desired locations, and the ability of insulators to block the flow of electrical energy."

This level of skill is very high, thus the concept of using two devices as taught by Gough et al ('143), rather than moving one around, which would take significantly more time, time during which the operating theater is not able to be used for other surgeries and during which the patient is under anesthesia, both of which are undesirable, since this makes waiting times for surgeries longer and it is desirable to minimize the time the patient is under anesthesia, since this can avoid deleterious reaction, official notice of all of which is hereby taken. Thus one of ordinary skill in the art, faced with the desirability of reducing operating room time and time under anesthesia for the patient, would easily determine that the use of two such devices as taught by Gough et al ('143) simultaneously would produce the same ablation patterns as those which Gough et al ('143) discusses producing by moving around a single device, in less time. Further, having made this determination, employing devices with a coaxial or side by side configuration to effect this time savings would also be easily within the grasp of one having such a high level of skill, the coaxial arrangement,

because this would enable the relative positions of the ends of the electrode outputs to be known with high precision, and the side by side configuration, because this would allow the treatment of tumors the axes if which are skewed with respect to the axes along which the devices are able to be inserted or which are irregularly shaped.

Turning now to applicant's arguments, with regard to the disclosure relating to Figures 7 and 8 of Gough et al ('143), applicant asserts that "Gough et al. '143 only shows a vertical plane of energization provided by two electrodes in each electrode set being in the plane of the paper on which Fig. 8 is presented" this is not convincing, however, as Gough et al. ('143) clearly discuss the use of 6 or more electrodes in the device, employing this number of electrodes would clearly "define a plane" as required by the claim. Applicant is respectfully reminded that the teachings of Gough et al. ('143) are not limited to the Figures therein, but include the written disclosure and the claims as well.

With regard to the discussion of the bipolar energization of the electrodes as discussed on page 6, as this portion of the office action was directed towards the teaching of providing insulation on the tip of the trocar and to show the possession and conveyance by Gough et al. ('143) to one of ordinary skill in the art, the knowledge that using a bipolar mode to allow current to flow from one electrode to the other along the axis of the device was known and desirable. In view of the latter teaching to provide multiple electrodes for multiplied effect (and to save time, as set forth above) would have been obvious (see St. Regis Paper Co. v. Bemis Co., Inc., 193 USPQ 8, 11). With regard to the two shafts having a particular construction that is in a coaxial or side by

side configuration, applicant argues that "this modification was not taught by the real world contemporaneous embodiments" and refers to the Haemmerich Declaration. The examiner must respectfully note that, as set forth in the response to this argument in the Haemmerich Declaration (and applicant is referred back to the response to these paragraphs in the Haemmerich Declaration for a more complete treatment of this matter), the claims are not rejected under the "real world contemporaneous embodiments" discussed by Declarant, but under the Gough et al ('143) reference, and in view of the teachings of this reference and the knowledge of one of ordinary skill in the art at the time of the invention, such a modification would have been obvious at the time of the invention, for the reasons set forth above. Continuing, applicant argues that the examiner's proposed modification of the Gough et al ('143) reference would be a modification of energizing one probe to energizing two. The examiner maintains the determination of obviousness, based on the time savings of using two probes simultaneously, rather than relocating a single probe, as set forth above, and in view of the obviousness of the provision of multiple parts for multiplied effect, as also set forth above. With regard to the issue of the electrodes being at predetermined spacings, applicant's arguments are somewhat confusing, in that applicant argues "that there is no teaching in Gough et al. '143 of kits with spacings for different sizes of tumors or presetting the spacing before handling of the device by a physician" (see the instant response, page 9, fourth full paragraph). This appears to be asserting that the provision of predetermined distances between the electrodes was unknown. However, looking at the reference to Gough et al ('143), clearly the embodiment where the more proximal

electrodes are extended through apertures in the shaft have a predetermined "spacing before handing of the device by the physician" unless applicant has found a passage in Gough et al ('143) that has eluded the examiner and directs the physician to machine these apertures in the device him- or herself in the operating room. Regardless of this, however, any limitation relating to who does the presetting is entirely absent from all the claims, and would likely be non-limiting in the case of the apparatus claims. Next applicant admonishes the examiner for his reliance on the level of one of ordinary skill in the art, noting that mere conclusory statements alone cannot sustain obviousness. The examiner respectfully notes that each statement relying on the knowledge and/or level of skill of one of ordinary skill in the art has been provided with a rationale supporting the conclusion, thus applicant's argument in this regard is not well founded.

The examiner will now address the features which applicant believes are not present in and/or are not obvious modifications of Gough et al ('143).

As to the limitation of two sets of three electrodes defining two respective axially spaced apart planes, it is the examiner's view that it would be obvious to modify e.g. the embodiment shown in Figures 5 or 8 to include 3 electrodes, due to both the obviousness of providing duplicate parts for multiplied effect (as determined in *St. Regis v. Bemis*, cited above) and the explicit teaching of providing more than 2 (i.e. 3, 4, 5, 6, or more) electrodes, as set forth in column 3, lines 20-25 of Gough et al ('143), discussed above. Further, one of ordinary skill in the art would be motivated to provide these electrodes equally spaced around the circumference of the shaft, since this would provide uniform treatment. Thus this limitation is clearly taught by Gough et al ('143),

and obvious under Gough et al ('143) in view of the knowledge of one of ordinary skill in the art.

As to the connection of the bipolar power supply between the two sets of three electrodes, it is the examiner's view that the broad statement in Gough et al ('143) that: "The number of deployed antennas can be four, five, six or more. Some of the antennas can be deployed out of the distal end of the trocar, while other antennas may be deployed from ports formed in the trocar along its longitudinal axis. The antennas may be RF electrodes operating in a monopolar mode, bipolar mode, or switchable between the two." (see column 3, lines 20-25), is sufficient to teach this. However, it is additionally noted that with regard to the embodiment of Figure 5 is specifically discussed as being able to "be operated in the bipolar mode between the two antennas" (see Gough et al ('143), column 8, lines 9-10). And in view of applicant's acknowledgement "that Fig. 8 of Gough et al. '143 only shows a vertical plane of energization provided by two electrodes in each electrode set being in the plane of the paper on which Fig. 8 is presented" (see the instant response, the first sentence of the paragraph bridging pages 7 and 8), these teachings coupled with the provision of more antennae, as discussed with regard to the previous perceived deficiency of Gough et al ('143), clearly teaches and/or renders obvious this limitation as well.

With regards to the limitation of "insulation of a support shaft between two electrode sets", as set forth above, it is the examiner's view that the provision of an additional device of any of the types taught by Gough et al ('143) in e.g. a side by side (or other) configuration would have been obvious to the artisan of ordinary skill in the

art, given the obviousness of providing duplicate parts for multiplied effect, as set forth above, and additionally, as already set forth, one of ordinary skill in the art is a surgeon familiar with radiofrequency ablation of tumors, and as such, the training for one of ordinary skill in the art would require not only 12 years of primary and secondary school, but 4 years of college, 4 more years of medical school, and additional years as an intern before qualifying as a surgeon qualified to ablate tumors with radiofrequency energy. Therefore, of necessity one of ordinary skill in the art would also be familiar with basic electrical principles, such as the relationship of current and power, the tendency for current to flow along many available paths, the appropriate connections required to cause electrical energy to be applied at the desired locations, the ability of insulators to block the flow of electrical energy, and the desirability of having the flow of energy blocked in certain locations and situations. Having established the level of skill of one of ordinary skill in the art, the information one of ordinary skill in the art would glean from the teachings of Gough et al ('143) will be determined. The establishment of the teaching and/or obviousness of providing at least three electrodes in each "set" and bipolar energization of the two sets with respect to one another have already been established above. Gough et al ('143) also teach that the electromagnetic delivery surface may be varied by varying the amount of the trocar and or antennas that are covered by the insulative sleeve, and that the insulative sleeve can contain apertures that permit the passage of antennae through the insulative sleeve while it is in place on the trocar, see column 5, lines 48-55:

"An insulation sleeve 18 may be positioned around an exterior of trocar 14 and/or antennas 16. All or some of insulation sleeves 18 may be adjustably positioned

so that the length of an antenna electromagnetic energy delivery surface can be varied. Each insulation sleeve 18 surrounding a trocar 14 can include one or more apertures. This permits the introduction of a antenna 16 through trocar 14 and insulation sleeve 18."

Gough et al ('143) also teach that when multiple antennae are used, they can produce "a substantially complete ablation volume formed between antennas 16 with a minimal core that is not ablated" (see Figure 4, and column 8, lines 2-4), as one of ordinary skill in the art would readily appreciate, the only way a non-ablated core can be produced is if there is no current flowing between the antennae and the trocar, if there were current flow, there would be commensurate ablation of tissue at the central core and this teaching would cause one of ordinary skill in the art to conclude that the trocar is insulated to produce this effect. Still further, Gough et al ('143) also teach that when multiple antennae are used, the antennae may be situated at different axial positions along the trocar and "can be operated in a bipolar mode between the two antennas 16, or between a antenna 16 and trocar 14" (see Figure 5, and column 5, lines 9-11). It will be readily apparent to one of ordinary skill in the art that if either or both of the antennae of the device of Figure 5 are energized as part of the bipolar energization thereof, when such energization is intended to be between the two antennae, current would also flow to the uninsulated trocar, the fact that Gough et al ('143) explicitly specify that that the bipolar mode can be between the antennae or the trocar would clearly indicate to one of ordinary skill in the art that that in the instance where the bipolar mode is between the antennae, the trocar must be insulated, else it, too would sink the current coming from the antennae. At this point the examiner must respectfully note that applicant has made much of the fact that Gough et al ('143) does

not expressly show insulation on the ends of the trocars, however, as the disclosure of Gough et al ('143) is written with the knowledge of one of ordinary skill in the art in mind, it is the examiner's view that the lack of showing of insulation in some cases is done for simplicity, with the understanding that one of ordinary skill in the art will readily recognize where insulation is necessary. As an example of this, the illustrations of the probes of Figures 4 and 5 show no insulation whatsoever. However, even assuming arguendo that one of ordinary skill in the art would not understand that the proximal portion of the device should be insulated, the moment the surgeon actuated the radiofrequency energy, and received a jolt from the uninsulated proximal portion of the shaft, the need for such insulation would become immediately apparent, even if the level of ordinary skill were such that one of ordinary skill in the art would not understand immediately that it should be done without being shocked. Similarly, when the exterior tissue of the patient began to smoke and ablate at the point where the proximal end of the device exited the patient, this would indicate to one of ordinary skill in the art that insulation at this point was in order. Essentially, the provision of insulation on metallic portions of the device which are expressly recited as not being desirable for receiving electrical current (e.g. the trocar of Figure 5 when the antennae alone are operated in bipolar mode) would have been obvious to one of ordinary skill in the art.

Concerning the limitation related to coaxial shafts, where each shaft is tubular metal with an insulated outer surface, applicant asserts this is not shown or suggested by Gough et al ('143). The examiner notes that the only passage located in the originally

filed disclosure that discusses the composition of the coaxial shafts was: "Shaft 18c and 42 are typically metallic and thus are coated with insulating coatings 45 and 46, respectively, to ensure that any current flow is between the exposed wires 32 rather than the shafts 18c and 42" (see the originally filed disclosure, page 10, first full paragraph, last sentence). Clearly the requirement for metallic shafts is not critical, but merely a matter of convention ("are typically metallic"). As already set forth in the art rejection, but repeated here for applicant's convenience: "it would have been obvious…to provide each shaft as a insulated metallic tubular member in a coaxial configuration, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and would make the device more sturdy" wherein the term "sturdy" is intended to encompass not only wearability, but also having the appropriate stiffness for the application.

Concerning the side-by-side shafts, this has been addressed above with respect to the provision of duplicate parts for multiplied effect and to save time.

Concerning the predetermined axial offset, this has been discussed with respect to the provision of cut outs in the trocar to allow antennae to be deployed at given (predetermined) distances from the antennae which are deployed from the end of the device. It can also be provided by employing a group of separate antennae which are of differing lengths, which would be obvious, since it would be unrealistic for one of ordinary skill in the art to expect all tumors to begin at a uniform depth beneath the skin and to have a uniform size or extent below the body surface.

Therefore, as can readily be seen from the foregoing, the examiner's assertions concerning both the teachings of Gough et al ('143) and that which would have been obvious to one of ordinary skill in the art, in view of the teachings contained in Gough et al ('143) are correct, therefore applicant's assertions and arguments based on the erroneous presumption that the teachings attributed to Gough et al ('143) and the obvious conclusions that one of ordinary skill in the art would draw therefrom, are not present therein, are not well founded.

With regard to what applicant refers to as "Factual issue No. 1", while Figure 8 can be made to read on the claims as set forth above, so can Figure 5 and any of the other embodiments when used in conjunction with another device of the same kind to save time, and which regardless of any time savings is obvious, as held in *St. Regis v. Bemis*, as set forth above. Concerning the limitations of claims 7, 8, and 22, also as set forth above, the provision of evenly distributed electrodes would have been obvious to the artisan of ordinary skill, since this would provide a uniform distribution of ablative energy. Thus applicant's conclusion is flawed

With regard to what applicant refers to as "Factual issue No. 2", applicant plucks another patent by Gough et al at random, which is neither in the chain of copendency of the reference which is actually applied to the claims, nor incorporated therein, in the hopes of obscuring the fact that Gough et al ('143) clearly and explicitly teach that the bipolar transfer of energy can occur either between the two antennae or between the antennae and the trocar, as set forth above. However, the absence of a teaching in an unrelated reference, which has never been applied to the claims, cannot

remove from the reference actually applied to the claims, the teaching which is explicitly recited therein. The reference to the Haemmerich Declaration, which instead of referring to a patent that has not been applied to the claims, refers to commercial products which have not been applied to the claims, is similarly unpersuasive, as set forth above.

With regard to what applicant refers to as "Factual issue No. 3", applicant "sincerely urges" that there is no evidence to support the notion that the trocar is insulated other than by sleeve 18. The examiner again refers to the passage at column 8, referring to Figure 4 and the knowledge of one of ordinary skill in the art, as set forth extensively above, and which will not be repeated here, for brevity. If applicant wishes to persuade the examiner that there is no teaching of insulation on the trocar in Figure 4 in Gough et al ('143), all applicant need do is explain exactly how the heating pattern expressly described at the top of column 8 therein would be produced in the absence of insulation on the trocar. Absent this, applicant's arguments are not convincing.

With regard to what applicant refers to as "Factual issue No. 4", the examiner acknowledges that the provision of two shafts, each composed of a metallic inner portion and an insulated outer portion is not taught by Gough et al ('143). However, the examiner also notes that this limitation is not critical and configuring the device of Gough et al ('143) as such would have been obvious to the artisan of ordinary skill, either by providing duplicate parts (i.e. duplicate multiple antenna devices) or by altering the composition of the two sheaths in Figures 7 or 8 to include both metal tubes (for strength, support, and rigidity) and insulators (to block the current from flowing

from the antennae into the support shaft via the tissue or any fluid infused, as disclosed with respect to Figure 6(c)). Applicant's assertion that the issue of criticality "is not seen to relate to combination claims in the electrical-mechanical arts unless a range or dimension is at issue" is noted, however, this assertion is erroneous. Applicant is referred to MPEP §716.02 - §716.02(g) and §2164.08(c), for example. A prima facie case of obviousness having been established by the examiner, by virtue of the rebuttal of the assertions and arguments submitted in the Haemmerich Declaration and applicant's remarks, the discussion of a lack of showing of unexpected results is appropriate. Thus this argument is not convincing.

With regard to what applicant refers to as "Factual issue No. 5", the examiner acknowledges that the provision of two shafts in a side-by-side configuration is not explicitly taught by Gough et al ('143), however, as set forth above it is an obvious variation of the Gough et al ('143) device and method, as it would save time over the use of a single device that was then moved around, and merely constitutes the provision of duplicate parts for multiplied effect as set forth in *St. Regis v. Bemis*. As with respect to "Factual issue No. 4", above, the discussion of the criticality and lack of unexpected results deriving from the limitation are proper and appropriate. Thus this argument is not convincing.

With regard to what applicant refers to as "Factual issue No. 6", applicant argues that the examiner misunderstands the claim limitation. The examiner believes he does understand the claim limitation. It is simply that when inserting two devices such as the devices taught by Gough et al ('143) (duplication of parts for multiplied effect

and/or to save time in the operating room and/or to minimize the time the patient is under anesthesia), this is what would be required to produce a non-predetermined spacing. Applicant has yet to explain in what way the trocars with apertures machined into them in addition to the terminal end of the trocar to provide for antenna placement does not constitute a "predetermined spacing". For example, the embodiment show in Figure 5 of Gough et al ('143) is manipulated, i.e. rotated, but the spacing of the electrodes is undeniably "predetermined". Thus applicant's arguments are not convincing."

6) The Disclosure of Gough ('143) Omits Details Which Would Be Understood By One Of Ordinary Skill In The Art

Firstly appellant alleges that the examiner "assumes the probes of Fig. 4 and 5 of Gough…are inoperative as described and enabled" (see the instant Brief, the first sentence on page 16). The examiner does nothing of the kind. The examiner recognizes that when patent applications are filed the teachings therein are directed to one of ordinary skill in the art, not to one who is completely unfamiliar with the subject matter being disclosed. As such, obvious details (for example that the patient is under anesthesia when undergoing the procedure) are not discussed, as they would be understood by those to whom the disclosure is directed. However, appellant asserts that the patient or physician would not be shocked by the current returning via the allegedly uninsulated trocar because "the uninsulated shaft is at ground potential" (see the instant Brief, the third sentence on page 16), alleging that the examiner has a "misunderstanding" of the operation of the Gough ('143). Interestingly, the term "ground" and its variants are entirely absent from the disclosure of Gough ('143). How

then would one of ordinary skill in the art, who is not "an expert in the field of electronics" as argued by appellants in section VII) (5), understand the concept of grounding, which is nowhere mentioned in Gough ('143), yet be totally confounded by the concept of using insulators to block current flow, a concept which is described repeatedly in Gough ('143)? This argument raises another interesting question, namely, why is insulation needed on the shafts of the instant device, if they can simply be held at ground potential? What is the advantage of incurring the extra cost and manufacturing complexity of producing a shaft with an insulative covering, when a simple ground connection would suffice? Another question that this assertion raises is why would Gough ('143) not employ insulation on the grounded trocar, in the embodiments where the energy is desired to be transmitted from one antenna to another as described at column 6, lines 18-19 "Electromagnetic energy can be delivered from one electrode to another"); column 7, lines 11-12 ("The volumetric ablation is created between the plurality of antennas 16"); column 8, lines 2-4 ("The effect is the creation of a substantially complete ablation volume formed between the antennas 16 with a minimal central core that is not ablated"); column 8, lines 9-10 ("Multiple antenna device can be operated in the bipolar mode between the two antennas 16"), if the trocar were grounded? Given these contradictions arising from appellant's theory that the trocar is grounded, particularly when no mention of grounding whatsoever occurs in Gough ('143), the examiner must respectfully submit that it is appellant, and not the examiner, who has misconstrued the teachings of Gough ('143). As such these arguments are not convincing.

(11) Related Proceedings Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

(12) Conclusion

It is the examiner's firm opinion that the appealed claims are not patentable for the reasons argued above. Appellant has presented no convincing argument as to why the rejections set forth above are not obvious or proper. Therefore, it is respectfully submitted that the final rejection be affirmed.

Respectfully submitted,

/david shay/

Primary Examiner, Art Unit 3769

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July 3, 2011

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